

REMARKS

Claims 2, 3, 5, 9, 13, 31 and 32 are herein amended. Claim 9 has been amended to remove a space.

New claim 34 has been added. Support for claim 34 is found in the Specification in figures 6 and 7 and in the Sequence Listing.

No new matter has been added.

Petition for a Suspension of Action and RCE

Applicants herein file a petition for a suspension of action for a period of three months under 37 C.F.R. 1.103(c). The appropriate fee under 37 C.F.R. 1.17(i) is authorized to be paid from deposit account Deposit Account No. 02-2448.

Specification Objections

The specification cross references priority documents as disclosed in the original PCT filing and WO publication. The statement incorporating those documents by reference has been removed.

No new matter has been added.

35 U.S.C. §112 Indefiniteness

The Examiner maintains her rejection of claims 2, 3, 5, 29, and 30 for the recitation of “or fragments thereof” in claims 2 and 3. Applicants have amended the claims to specify the fragments’ origin. Applicants respectfully request that the rejection be withdrawn.

The Examiner rejects claim 13; Applicants have inserted “monoclonal antibodies produced by the hybridomas ATCC HB 9324 or ATCC HB 9347.” Applicants request that the rejection be withdrawn.

The Examiner rejects claims 1-3, 5, 9, 13 and 29-32 as being indefinite for omitting “sequence” in claim 1. Applicants have amended the claims. Applicants request that the rejection be withdrawn.

35 U.S.C. §112 Enablement: Biological Deposit

The Examiner rejects claim 13 because the specification does not enable one skilled in the art to make and use the invention because the specification does not provide evidence that the claimed biological materials are a) known and readily available to the public or b) reproducible from the specification. Applicants respectfully traverse.

Applicants herein provide a copy of the ATCC catalog showing that the two hybridomas are available for purchase. Applicants request that the rejection be withdrawn.

35 U.S.C. §112 Enablement

The Examiner rejects claims 1-3, 5, 9, 11-13, 29, and 30 because the specification does not reasonably provide enablement for any antibody comprising “at least part of a murine IgG2a subtype sequence” or an IgG1 antibody containing any part of a murine IgG2a subtype within the constant domain which still retains antigen binding and immunogenicity.

The Examiner concedes that the Specification is enabling “for an anti-idiotypic antibody for the Lewis-Y antigen where the recombinant IgG2a Le-Y antibody is an IgG2a hybrid designed for primate vaccination, which combines an anti-idiotypic Lewis-Y mimicking hypervariable [sic] region and the highly immunogenic mouse IgG2a constant regions as shown in Figure 4.” (Office Action, page 11). However, the Examiner is concerned that “[i]t is not well established in the art that an antibody encompassed by the claims is amenable to the extent and degree of the modifications to the Fc or constant domain that would allow proper folding and assembly of this antibody, and the specification is not any more enabling for producing a functional, immunogenic antibody that meets all of the claim limitations.” (Office Action, page 12).

The Examiner suggests that a) adding a glycosylation site at any position on the antibody could lead to protein aggregation or improper folding of the antibody, b) that adding the IgG2a sequence anywhere in the antibody would affect the resultant hybrid antibody's stability, binding, and functionality.

With regard to a), Applicants note that page 12, lines 10-16 of the Specification discloses that the antibodies of the invention are coupled to a carbohydrate residue.

With regard to b) and the insertion of the IgG2a sequence, the Specification discloses that the antibody may have a murine amino acid sequence or any other mammalian amino acid sequence that is combined with the murine IgG2a part. (Specification, page 9, paragraph 4). The Specification indicates that the preferred location of the IgG2a sequences in a hybrid antibody is in any one of the CL, CH1, hinge, CH2, and CH3 regions, though the hinge region is most preferred. (Specification, page 14, paragraph 2).

Applicants also point out that a fully functional antibody, having two heavy chains and two light chains is not necessary to raise an immune response against the antibody, because the invention uses the antibodies as a "carrier" to deliver an antigen mimetic and/or immunogenic glycosylation. Accordingly, Applicants request that the rejection be withdrawn.

Claim Objections

The Examiner objects to claims 31-32 for the recitation of Globe rather than Globo. Applicants have amended the claim and request that the objection be withdrawn.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By 

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Attachment: ATCC Catalog Pages